K063047

Exhibit C

510(k) Summary

OCT 19 2006

Name and address of sponsor of the 510(k) submission:	MedHot Thermal Imaging, Inc. 315 Doris Drive, Lakeland. Florida - 33813
Official contact person for all correspondence:	Carol Chandler (address as above) Phone: 863 709 9565, Fax: 863 619 7525 E-mail: infrared@tampabay.rr.com
Date Prepared:	Sept 27, 2006
Device Name:	MedHot MTI 2000 Thermal Imaging System
Generic name of the device:	Telethermographic System (Adjunctive)
Classification, Product Code and CFR Regulation Number:	Class I, LHQ and 21 CFR 884.2980
Classification Panel:	Obstetrics/Gynecology
Predicate Device Name:	Telethermographic camera Series A, E, P, and S
Predicate 510(k) Number:	k033967

Device Description:

The MedHot MTI 2000 thermal imaging system is a non-invasive system that provides the user a visual representation of thermal temperature data in the form of a quantitative image on the users computer screen. The process begins by the cameras' capture of a data array representative of infrared radiation naturally emitted by the object being imaged; the data array is converted to a temperature data array using an algorithmic derivative. Once the infrared data is in the form of temperature data, software on the user's computer is used to generate an image from the rendered temperature data. The user can use this image in a number of ways to quantify the temperature of objects imaged.

Comparison of Technological Characteristics to Predicate Device:

	MedHot MTI 2000	A20M
Technology / Detector	FPA UC Microbolometer	FPA UC Microbolometer
Material	Amorphous Silicon	Amorphous Silicon
Spectral Response	7-14 µm	7.5-13 µm
Thermal Sensitivity	< 100 mK	< 80 mK
Contrast / Brightness	Software Controlled	Software Controlled
Data Output	Analog NTSC Video	IEEE-1394 usb firewire
Refresh Rate	20 fps Refresh	60 fps Refresh
Optics	8.5mm with 50°x 35°	24° x 18°/ 0.3 m
Array Resolution	160x120 array	320x240 array
Focus	manual	manual
Power Supply	2.0 amps @100 VAC	AC adapter 110/220 VAC, 50/60Hz
Weight	2.5 pounds	1.7 pounds
Size	7.6" / 5.0" / 2.2"	6.2" / 2.9" / 3.1"
Operating Temperatures	"-20°C to +60°C (-4°F to +140°F)"	"-40°C to +70°C (-40°F to +158°F)"
Emissivity Correction	Variable from 0.1 to 1.0	Variable from 0.1 to 1.0
Method of Data Collection		
collection instrumentation		
data processing	camera and computer each have onboard cpu's	camera and computer each have onboard cpu's
Measurement Parameters		
storage	data storage on computer	data storage on computer
Camera Output		
display	GUI on computer	GUI on computer
user interface	Software on computer	Software on computer

Intended Use:

Intended for qualified healthcare personnel who are trained in its use; The MedHot MTI 2000 is a non-contact, non-invasive, non-radiating, thermographic imaging device for use as an adjunct to other clinical diagnostic procedures in the capture, quantification, and screening, of differences in skin surface temperature changes.

The device can digitally render quantitative images of thermal data via the capture and algorithmic interpretation of relative infrared information from the imaging camera in collaborative use with a compatible computer system which provides a user interface and image storage.

Patient populations and environmental use includes all age groups from adult to pediatric and neonatal in hospital, sub acute and public areas i.e. airports.

Non-Clinical Testing:

Camera unit was successfully tested for EMC and EMI compliance as per IEC 60601-1-2 requirements. Power supply also conforms to appropriate medical grade standards.

Clinical Testing:

Not applicable

Conclusion:

MedHot MTI 2000 is substantially equivalent to the predicate device and arguments given in the submission show that the differences don't bring up any new questions regarding the safety and effectiveness of the subject device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MedHot Thermal Imaging, Inc.
c/o Mr. Robert Mosenkis
President
CITECH
5200 Butler Pike
PLYMOUTH MEETING PA 19462-1298

OCT 19 2006

Re: K063047
Trade/Device Name: MedHot MTI 2000 Thermal Imaging System
Regulation Number: 21 CFR §884.2980
Regulation Name: Telethermographic system
Regulatory Class: I
Product Code: LHQ
Dated: September 27, 2006
Received: October 4, 2006

Dear Mr. Mosenkis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Exhibit B

INDICATIONS FOR USE

510(k) Number (if known): ~~Not Assigned as of this time~~ K063047

Device Name: MedHot MTI 2000 Thermal Imaging System

Indications for Use:

Intended for qualified healthcare personnel who are trained in its use, the MedHot MTI 2000 is a non-contact, non-invasive, non-radiating, thermographic imaging device for use as an adjunct to other clinical diagnostic procedures in the capture, quantification, and screening, of differences in skin surface temperature changes.

The device can digitally render quantitative images of thermal data via the capture and algorithmic interpretation of relative infrared information from the imaging camera in collaborative use with a compatible computer system which provides a user interface and image storage.

Patient populations and environmental use includes all age groups from adult to pediatric and neonatal in hospital, sub acute and public areas i.e. airports.

Prescription Use ✓ **OR** **Over-The Counter Use** ____
(Per 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K063047